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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SAKELARIS, SALLY A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,599	Applicant(s) KAUTZ ET AL.	
	Examiner Sally A. Sakelaris	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/29/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The phrase "closely approaching zero" in claim 1 is a relative term which renders the claim indefinite. The phrase "closely approaching zero" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of that which applicant considers "close".
2. Claim 1, 2, 6, and 10 recite the phrase "the conditions in step c)" followed by either a recitation of "(a favorable surface)" or "(an unfavorable surface)". First it is unclear how the same conditions in step c can result in vastly different surfaces, one being favorable and one not. Second, the recitations of favorable or unfavorable are not located within step c of the claim so it is unclear exactly how the limitations within step c are responsible for the favorable or unfavorable nature of the surface. Applicant should amend the claims to recite the actual conditions (ie, the surface coating that is present/absent) of their conduit system.
3. Claims 1, 2, 6, and 10 recite the phrase "inherently capable of satisfying the conditions". It is not clear if the wall surface is inherently capable of satisfying these

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conditions or if the coating on the surface is that which confers the “hydrophobic” or “non-wetting” ability to the interior wall surface. Applicant should clarify what part of their method’s device is responsible for the inherent trait and what this inherent trait is.

4. Claims 1, 2, 6, 9, and 10 recite “(a favorable surface)” or “(an unfavorable surface)”. It is not clear how a favorable surface is favorable or how an unfavorable surface is unfavorable. It is not clear if favorable connotes a hydrophilic or hydrophobic nature to the surface and furthermore how this nature creates a desired or discouraged condition for the method. Applicant should amend the claims to clarify that which is making their surfaces favorable or unfavorable by better defining these conditions.

5. Claim 10 contains the trademark/trade name Teflon™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polytetrafluoroethylene and, accordingly, the identification/description is indefinite.

6. Claim 1 does not recite a clear nexus between the preamble and the final process step. The claim is drawn to method of moving small samples of liquid through a microscale conduit system. However, the final step is one to insure that the internal wall

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surface of a section of the conduit system has satisfied conditions of step c). The claims do not clearly set forth how the condition of the internal wall results in the movement of small samples of liquid through the microscale conduit system.

Accordingly, it is not clear as to whether the claims are intended to be limited to methods for moving liquid or to meeting the conditions of step c). Applicant should clarify their intentions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, and 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Kellogg et al. (US Patent 6,706,519).

With regard to claims 1-4, Kellogg et al. teach methods for performing various microanalytic and microsynthetic analyses and procedures. Kellogg teaches the addition of various liquids comprised of solvents and liquids that are immiscible with liquid samples. This use of their platform for various applications can be seen in FIGS 1-5 and within the examples of the disclosure. The liquid samples accepted by the platforms include raw, pre-diluted, and biological fluids containing mammalian, bacterial and eukaryotic cells. The device can be used for a suite of biological reactions

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including DNA isolation, amplification and PCR (Col. 35 lines 19-37) all consisting of their characteristic reagents. The microchannels of the device are filled with various hydrophilic solvents (water, plasma, ethanol, elution buffer – Col. 43 lines 35-60) and hydrophobic, immiscible fluids (SDS, lysis mixture, proteins, non-polar cellular components – Col. 43 lines 35-60). These fluids are transferred at will from one chamber to another for mixing purposes, addition, and detection. Kellogg et al. also teach their conduit system to be constructed of either wetting or non-wetting materials where appropriate (Col. 9 lines 58-60). Kellogg teaches that the surface properties of their platforms may be added in layers and that these materials may be modified for specific applications (Col. 15 line 35-38). In some embodiments microchannel 1033 is treated to present a hydrophobic surface resistant to wetting fluids (Col. 24 lines 52-54). Kellogg teaches that elution buffer is driven through microchannels 1044 and 1026, the topography or the hydrophobic coating of the microchannel 1033 prevents the fluid from flowing into the waste reservoir (Col. 29 lines 43-49). In one embodiment, Kellogg teaches that a capillary junction is formed using a component having differential surface treatment of a capillary or flow path:

“For example, a channel that is hydrophilic (that is, wettable) may be treated to have discrete regions of hydrophobicity (that is, non-wettable). A fluid flowing through such a channel will do so through the hydrophilic areas, while flow will be impeded as the fluid-vapor meniscus impinges upon the hydrophobic zone.” (Col.10 lines 57-67).

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With regard to claims 11-13, Kellogg's conduit system permits mixing and valving performed as a consequence of the structural arrangements of the components on the platforms (such as shape, length, surface properties of the interior surfaces of the components, such as wettability as discussed previously) (Col. 6 lines 60-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claim 15-19, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (US Patent 6,706,519).

Kellogg et al. teaches the above methods involving provisions of liquid samples, immiscible fluids and various steps of transferring of these reagents.

Kellogg does not teach each step's repetition.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the steps in claims 15-19 since mere

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duplication of parts or process steps has no patentable significance, unless a new and unexpected result is produced, since it involves only routine skill in the art.

9. Claims 5, 10, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (US Patent 6,706,519) in view of Behnia et al. (Anal. Chem. 1998, 70, 5326-5331).

Kellogg's teaching may be seen above.

Kellogg does not teach a carrier liquid that is perfluorocarbon, a conduit system comprising Teflon™, or that the microfluidic device is a probe for an NMR spectrometer wherein the observed volume of the detection cell is included in the device.

Behnia et al. teach a method of limited sample NMR using 2 liquid perfluorocarbon plugs as a carrier fluid around the sample (Title and abstract).

Behnia et al teach in Figure 3, configuration C, the sample plug was bracketed on both sides by solid Teflon™ beading.

With regard to claim 14, Behnia et al teach in Figure 1 the schematic for the spinner probe of an NMR experiment and in Figure 4 teach the multiple different sample and plug configurations for the spinner probe method and assembly.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the microfluidic device of Kellogg for the NMR probe of Behnia, perfluorocarbon as the carrier fluid, and tubing comprising Teflon™ as these adjustments greatly improve the quality of NMR spectra from mass-limited samples since given a limited amount of sample, the signal received from the

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sample is maximized when the sample is concentrated in the minimum volume of solvent possible as well as allowing quick sample changing which is a prerequisite for many industrial applications.

10. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (US Patent 6,706,519) in view of Behnia et al. (Anal. Chem. 1998, 70, 5326-5331) in further view of Yang.

The methods of Kellogg in view of Behnia is shown above and include their teaching of a glass or silica based microfluidic system where perfluorocarbon as the carrier fluid.

The method of Kellogg in view of Behnia do not teach that their method's device being coated with a fluoroalkyl silane.

Yang teaches a method of coating devices with an anti-wetting coating wherein the coating agent is an alkyl or fluoroalkyl silane compound.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the method of Yang to coat the microfluidic device of Kellogg in view of Behnia with an fluoroalkyl silane for the expected benefit of reducing the surface energy of the miniature structural members to improve the device's performance (Col 1 lines 26-48).

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (US Patent 6,706,519) in view of Yang (US Patent 6808745).

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Kellogg's teaching may be seen above.

Kellogg does not teach a coating of fluoroalkyl silane.

Yang teaches a method of coating devices with an anti-wetting coating wherein the coating agent is an alkyl or fluoroalkyl silane compound.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the method of Yang to coat the microfluidic device of Kellogg with an fluoroalkyl silane for the expected benefit of reducing the surface energy of the miniature structural members to improve the device's performance (Col 1 lines 26-48).

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (US Patent 6,706,519) in view of Behnia et al.(Anal. Chem. 1998, 70, 5326-5331) in further view of Yang and in an even further view of Anderson (US Patent 6645432).

Kellogg in view of Behnia, and in further view of Yang may be seen above.

Kellogg in view of Behnia, and in further view of Yang does not teach a tridecafluoro-1,1,2,2-tetrahydrooctyl-1-trichlorosilane coating.

Anderson teaches silanizing their surface by applying a tridecafluoro-1,1,2,2-tetrahydrooctyl-1-trichlorosilane coating (Column 44, lines 24 and 25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the coating method of Anderson in the method of moving small samples in a microfluidic device as taught by Kellogg in view of

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Behnia and in further view of Yang for the expected benefit of reducing the surface energy of the miniature structural members to improve the device's performance.

13. Claim 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (US Patent 6,706,519) in view Yang (US Patent 6808745).

Kellogg's teaching of their silicon microfluidic device may be seen above and in Fig.1-4.

Kellogg does not teach a coating of fluoroalkyl silane on their device.

Yang teaches a method of coating devices with an anti-wetting coating wherein the coating agent is an alkyl or fluoroalkyl silane compound.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the method of Yang to coat the microfluidic device of Kellogg with an fluoroalkyl silane for the expected benefit of reducing the surface energy of the miniature structural members to improve the device's performance (Col 1 lines 26-48).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 5712726297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 5712721267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sally Sakelarlis

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797